

**PATENT APPLICATION**  
**PHARMACEUTICAL DISTRIBUTION DEVICE**

Inventor(s): Nancy G. Pile,  
Citizen of United States, Residing at  
817 Ridgeview Drive  
Mill Valley, CA 94941

Assignee: MedStep Health Services, Inc.

Entity: Small business concern



Wilson Sonsini Goodrich & Rosati  
PROFESSIONAL CORPORATION

650 Page Mill Road  
Palo Alto, CA 94304  
(650) 493-9300  
(650) 493-6811

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## **PHARMACEUTICAL DISTRIBUTION DEVICE**

### **BACKGROUND OF THE INVENTION**

- [0001] The invention relates generally to kits for complex drug regimens and methods of providing complex drug regimen items, such as methods and kits for fertility treatment regimens.
- [0002] Fertility enhancement treatment requires the self-administration of a variety of drugs in a prescribed manner, order and dosage according to a specified schedule. Mistakes in the manner, order and/or dosage of fertility drugs may result in a reduced efficacy of the treatment.
- [0003] More significantly, the psychological stress level of the woman undergoing fertility enhancement treatment can affect the outcome of the treatment. Higher levels of psychological stress have been linked to reduced positive outcomes. See, e.g., “DeStress for (Fertility) Success,” HealthScoutNews June 29, 2001; “What Is the Stress/Infertility Connection?”, an online chat dated June 2, 2003 and viewable at <http://www.resolve.org/main/national/bboard/chat030602.jsp>.
- [0004] Koestermann et al. U.S. Patent Application Publ. No. 2003/0211627 describes a method and apparatus for managing a fertility kit. The patent application describes a box with compartments for storing medications and ancillary devices. A doctor’s prescription, orders and instructions may be placed on the inside of the box’s lid.
- [0005] One drawback of this and other prior art complex drug regimen kits is their failure to adequately and positively identify the drugs and ancillary devices to be used in the regimen. For example, the order, dosage and timing of the drugs to be taken during fertility treatments can be difficult to follow. While the fertility kit described in the Koestermann et al. patent application provides a prescription, orders or instructions, the kit does not sufficiently tie drug names or other identification information to the corresponding drugs, nor does it tie ancillary devices, such as syringes, to the drugs to which they correspond. Psychological stress from uncertainty about which drugs and/or drug devices in the Koestermann fertility kit to use at a particular point in the treatment regimen, as well as actual treatment errors from choosing the wrong drug or device, can lead to reduced treatment efficacy.

[0006] Another drawback of earlier complex drug regimen kits is their relative inadaptability to changes in the drug regimen, such as changes to the drug contents, container sizes, etc. For example, the Koestermann et al. patent application describes the alteration of drug compartment sizes by cutting foam rubber material to accept the drugs and ancillary devices to be stored in them. This approach to constructing the kit is unduly inflexible and cumbersome.

### SUMMARY OF THE INVENTION

[0007] The invention provides a complex drug regimen kit and method for providing drugs for a complex drug regimen that is easier to make and use. One aspect of the invention provides a method of providing items required for a complex drug regimen. In a preferred embodiment, the method includes the steps of disposing a plurality of different drugs in corresponding drug compartments within a container and providing drug identification information visually associated with each drug compartment containing a drug. The method may also include the step of labeling the drug compartments with labels to identify drugs to be taken together. In embodiments in which at least two of the drugs are intended to be used together, the disposing step may include the step of associating the at least two drugs with the same label.

[0008] The method may also include the step of altering a drug compartment size prior to completion of the disposing step, such as by adding or removing a wall portion of a compartment from the container or by adding or removing a false bottom to the drug compartment.

[0009] In some embodiments the disposing step may include the step of disposing a drug delivery tool with a drug in a compartment. The invention may also include the step of arranging the drug compartments in a drug compartment arrangement following an intended order of use, and the step of providing drug identification information may include the step of providing drug identification information arranged in an arrangement substantially similar to the drug compartment arrangement. The step of providing instructions may include labeling the container, such as on the container's lid.

[0010] Another aspect of the invention provides a kit for a complex drug regimen. In a preferred embodiment the kit includes: a kit container comprising a plurality of drug compartments, each drug compartment adapted to contain one or more drugs; a plurality

of different drugs disposed in the drug compartments; and drug identification information visually associated with each drug compartment containing a drug. In some embodiments, the kit includes at least one label identifying drugs to be taken together. For example, if at least two of the drugs are intended to be used together, both may be associated with the label. In some embodiments the kit also includes at least one drug delivery tool disposed in a drug delivery compartment along with a drug, such as by placing the drug and its corresponding tool in an order of use within the drug compartment.

[0011] The drug compartments may be arranged in a drug compartment arrangement following an intended order of use, and the drug identification information may be arranged in an arrangement substantially similar to the drug compartment arrangement. In embodiments in which the kit container has a lid, the instructions of use may be disposed on the lid.

[0012] In some embodiments at least one drug compartment is adapted to be altered in size, such as by inserting or removing a drug compartment wall portion or false bottom. The kit may also have a biohazard container. In some embodiments, the kit container may be adapted to conceal most of the biohazard container from view when the kit container's lid is open. For example, the kit container may be adapted to conceal from view substantially all of the biohazard container except for its lid.

#### **INCORPORATION BY REFERENCE**

[0013] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

[0014] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0015] Figure 1 is a schematic drawing of a kit for a complex drug regimen according to one embodiment of the invention.

[0016] Figure 2 is a schematic drawing of a kit for a complex drug regimen according to another embodiment of the invention.

[0017] Figure 3 is a schematic drawing of the kit of Figure 2 showing a cross-section taken along line A-A in Figure 2.

[0018] Figure 4 is a schematic drawing of the kit of Figure 2 loaded in a mailing container.

[0019] Figure 5 is a schematic drawing of a kit according to another embodiment of the invention, loaded in a mailing container.

#### **DETAILED DESCRIPTION OF THE INVENTION**

[0020] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

[0021] Figure 1 shows one embodiment of the invention. A complex drug regimen kit 10, such as a kit containing drugs for fertility treatment, contains drugs 12, drug delivery devices 14 and other drug regimen materials arranged in drug compartments 16 formed within a box 18 or other container. The drug compartments are preferably arranged in the order in which the drugs are to be taken. Drug delivery devices or other materials needed to be used when taking a particular drug are disposed in the same compartment as the drug, such as an injectable drug and the syringe used when injecting the drug.

[0022] In this embodiment the drugs 12 and their corresponding drug delivery devices 14 are arranged in the order of their use. For example, the syringes 14 used for injectable drugs 12 are placed in front of the corresponding drugs in drug compartment 16, as shown in Figure 1.

[0023] Drug identification information is also provided in the kit. In a preferred embodiment, the drug identification information is visually associated with the drugs to which it pertains. This visual association makes it easier to follow the drug regimen. For example, box 18 in Figure 1 has a lid 20 on which the drug identification information 22 is labeled. To create the visual association between the drug identification information and the corresponding drugs, the drug identification information is arranged in an arrangement substantially similar to the drug compartment arrangement, such as in information areas 24. This visual association reduces doubt about which drug identification information pertains to which drugs.

[0024] The drug identification information can also be used to create a common language between the patient and health care professionals. For example, one or more of the information area rectangles 24 can be labeled as "Step 1," "Step 2," etc., in place of or in addition to listing the drugs and devices contained in the corresponding drug compartments. When the patient is speaking with a health care professional about the drug regimen, the patient can refer to a step rather than try to identify or pronounce the drug or ancillary device name.

[0025] In addition, stress reduction materials 26, such as pamphlets, video tapes, etc., may be provided in the kit. These stress reduction materials are part of an overall program to increase the efficacy of the drug treatment.

[0026] One particularly stressful aspect of drug regimens that include injectable drugs is the disposal of the syringes or other sharps. State and federal sharps regulations require sharps disposal in clearly marked biohazard containers. Just seeing the biohazard warning label can be a stressor; handling the container itself can be even worse. The kit of this invention therefore provides a sharps disposal biohazard container 28 that is preferably mostly concealed from view by box 18. In the embodiment of Figure 1, box 18 conceals the sharps container's biohazard warning label, and sharps may be deposited in the sharps container without removing the container from box 18. As shown in the embodiment of Figure 1, box 18 conceals substantially all of the biohazard container 28 except for its lid 30.

[0027] Not all drug regimens are alike, of course. The invention therefore provides a way to customize the kit container to the contents. In the embodiment shown in Figure 1,

one or more of the walls 32 of drug compartments 16 may be added or removed to change the shape and size of the drug compartment.

[0028] The invention also provides a way to easily mail a complex drug regimen kit. Lid 20 of box 18 has a hinged flap 34 that folds down over the front 36 of box 18 when lid 20 is closed. Fasteners 38 (such as hook and loop fasteners) are disposed on flap 34 and box front 36 to keep lid 20 closed. Box 18 may then be placed in a mailing container to send to the patient.

[0029] To facilitate mailing, box 18 preferably is sized to fit within a standard express mail box. In one embodiment, box 18 has a dimension along edge 40 of about 16.75 inches or less, a dimension along edge 42 of about 16.75 inches or less and a dimension along edge 44 of about 6.75 inches or less. In another embodiment, box 18 has a dimension of 17.25 inches or less along one side, a second dimension of about 12.25 inches or less along another side and a third dimension of about 2.875 inches or less. Other dimensions corresponding to other mailing container sizes may be used without departing from the invention, of course.

[0030] Figure 2 shows another embodiment of a complex drug regimen kit. Kit 100 has a container 102 with a plurality of drug compartments. The drug compartments are grouped to identify drugs to be taken together, such as drugs to be taken within the same time period or as part of the single step of a complex drug regimen. In this embodiment, the drug compartments are labeled to show groupings of related drugs and drug devices. Thus, drug compartment 104 has a label 106; drug compartments 108, 110 and 112 have a label 114; drug compartments 116 and 118 have a label 120; drug compartments 122, 124, 126, 128 and 130 have a label 132; and drug compartments 134, 136 and 138 have a label 140. In addition to helping group the drugs and drug devices by order of use, the labels also provide a common language between the patient and a healthcare professional with regard to the drugs and drug devices by providing a convenient way of referring to the drugs and devices without having to use medical terms or chemical names.

[0031] For example, a fertility kit made and used according to this invention could be assembled as follows: Label 106 reads "Step 1," and drug compartment 104 contains drugs and devices relating to one particular phase of a fertility treatment, ovarian control. The corresponding drug identification information is shown in Table 1, where the ovarian

control medications are identified under a similar label reading “Step 1”. Note that in this embodiment the drug identification information is set forth in a format that mimics the layout of the kit’s container. This drug identification information may be disposed on the inside of the container’s lid, as in the Figure 1 embodiment, or may be provided with the kit as a separate piece. If a patient has a question about the drugs taken in this phase of the treatment, she may simply refer to the “Step 1 drugs” instead of having to use their chemical names. This common and easy to use language reduces the stress associated with fertility treatments and helps increase the likelihood of a positive treatment outcome. Use of a common language also reduces the amount of time spent by patients and their health care providers during telephone calls, training sessions, etc.

[0032] TABLE 1

STEP 1	STEP 2		STEP 3	
<u>Ovarian Control</u>  As Needed: One of these medicines: <i>Lupron</i> <i>Synarel</i>	<u>A. Stimulation Medicines</u>  One or two of these medicines: <i>Gonal F</i> <i>Gonal F Multidose</i> <i>Follistim</i> <i>Bravelle</i> <i>Repronex</i> <i>Pergonal</i>		As Needed: <i>Antibiotics</i> for male Other pills <u>HCG Medication</u>	
			Syringe & Mixing Needle For HCG	Injection Needle For HCG
<b>ALL STEPS</b>			<b>STEP 4</b>	
As Needed: <i>Antibiotics</i> <i>Baby Aspirin</i>	<u>B. Antagonist Ovarian Control</u>  If Skipped Step 1 then also one of these medicines: <i>Antagon</i> <i>Cetrotide</i>		As Needed: <u>Progesterone Pills</u>	
Alcohol Pads	<u>C. As Needed</u>  <i>Viagra Suppositories</i>		Unused space	
Sharps  For needle disposal only	Syringes & Mixing Needles For Stimulation Medicines	Injection Needles and Gauze Pads for Stimulation Medicines	Syringes & Mixing Needles For Progesterone	Injection Needles For Progesterone



[0033] Continuing the example, label 114 reads "Step 2," and the drugs and devices in the corresponding drug compartments 108, 110 and 112 contain drugs and devices related to another phase of the fertility treatment; label 120 reads "Step 3," and the drugs and devices in corresponding drug compartments 116 and 118 relate to yet another phase of the fertility treatment; and label 132 reads "Step 4," and the drugs and devices in corresponding drug compartments 122, 124, 126, 128 and 130 relate to still another phase of the fertility treatment. Finally, label 140 reads "All Steps," meaning the drugs and devices in drug compartments 134, 136 and 138 may be used during any or all phases of the fertility treatment.

[0034] As in the embodiment of Figure 1, the kit container of this embodiment may be customized by changing the size and shape of the drug compartments, such as by adding and/or removing drug compartment walls. In addition, a false bottom may be added to any drug compartment or part of a drug compartment to raise a drug or drug device up, e.g., level with other kit contents. Thus, as shown in Figure 3, false bottoms 142 and 144 have been added to drug compartments 112 and 130, respectively. In addition, inserts may be placed within a drug compartment to hold and support a drug bottle, device, etc., such as insert 146 in drug compartment 116, as shown in Figure 2.

[0035] Figure 4 shows a complex drug regimen box 200 disposed within a mailing container 202. As shown, mailing container 202 is a standard overnight shipping box having one or more flaps 204 which, when opened, expose complex drug regimen box 200. To facilitate removal of box 200 from mailing container 202, one or more tabs 206 are attached to box 200, such as by punching out portions of box lid 208. Tabs 206 provide grips for removal of box 200 from container 202. Alternatively, a strap may be wrapped around three sides of box 200 within mailing container 202 with the ends of the straps extending from the open end of mailing container 202.

[0036] Figure 5 shows a complex drug regimen tray 300 disposed in a mailing container 302, such as a standard overnight shipping box. Once again, tabs 304 are attached to tray 300 to facilitate removal of tray 300 from mailing container 302.